

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
(SHERMAN DIVISION)**

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UNITED STATES OF AMERICA and  
THE STATE OF TEXAS *ex rel.* DERRICK  
NGUYEN, M.D.,

Plaintiffs,

vs.

**Civil Action No. 4:15-cv-00814-ALM**

McKESSON CORPORATION, a  
Delaware corporation; U.S. ONCOLOGY  
INC., a subsidiary of McKesson  
Corporation; TEXAS ONCOLOGY, P.A., a  
Texas professional association; and  
DENNIS J. COSTA, M.D.,

**JURY TRIAL DEMANDED**

Defendants.

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**FIRST AMENDED COMPLAINT FOR VIOLATION OF FALSE CLAIMS ACT  
(31 U.S.C. §§3729 *et seq.*) AND TEXAS MEDICAID FRAUD PREVENTION ACT  
(TEX. HUM. RES. CODE ANN. § 36.002 *et seq.*)  
TRIAL BY JURY REQUESTED**

On behalf of the United States of America pursuant to the United States False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“FCA”), and the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code. Ann. §§ 36.001 *et seq.* (“TMFPA”), Plaintiff-Relator Derrick Nguyen, M.D. files this *qui tam* Complaint for treble damages and civil money penalties against defendants Texas Oncology, P.A. (“TOPA”), McKesson, The US Oncology Network, and Dennis J. Costa, M.D. (“Defendant Costa”) (collectively, “Defendants”). These claims arise from Defendants’ knowing and reckless submission of false and fraudulent claims to federal health care programs and from Defendant Costa’s knowingly and recklessly causing the submission of such claims. In support of these claims, Relator alleges as follows:

## **INTRODUCTION**

1. The fraud at issue in this case concerns Defendant Costa's excessive administration of two chemotherapy drugs: Rituximab and intravenous immune globulin ("IVIG"). The relevant medical literature and standards of oncology practice establish clear guidelines for the use of these drugs based on extensive research regarding their efficacy and safety.

2. As discussed below, Defendant Costa's departure from those guidelines was frequent, extreme, and unethical. As a result, numerous patients received many times the recommended doses of these drugs, subjecting them to serious complications or significantly increased risk of severe complications. This is not a case concerning medical judgment about which reasonable oncologists could disagree. This case is about a regular practice and pattern of administering expensive chemotherapy drugs in ways that cannot be justified by any medical guideline whatsoever, all in the name of increasing revenue at the expense of patient safety.

3. For over 20 years, Defendant Costa has worked as senior partner and one of the founding members of TOPA.

4. TOPA takes a direct 30% overhead management expense from its physicians. By doing so, TOPA manages the practice and accepts liability for any actions incurred by its constituents or partners.

5. At all relevant times, TOPA knowingly and recklessly billed Medicare and Medicaid for Defendant Costa's improper drug administration in contravention of federal and state regulations and contrary to its own internal medication administration guidelines.

6. At all relevant times, McKesson Corporation knew or should have known that

TOPA knowingly and recklessly billed Medicare and Medicaid for Defendant Costa's improper drug administration in contravention of federal and state regulations and contrary to its adopted guidelines establishing the standard of care for administration of maintenance drugs to patients.

7. At all relevant times, The US Oncology Network knew or should have known that TOPA knowingly and recklessly billed Medicare and Medicaid for Defendant Costa's improper drug administration in contravention of federal and state regulations and contrary to its adopted guidelines establishing the standard of care for administration of maintenance drugs to patients.

8. Through the above and other actions, Defendant Costa, the community-based practices, and parent corporations tasked with oversight intentionally defrauded the federal government and the State of Texas by improperly submitting or causing to be submitted claims for payment and then retaining the payments to which they were not entitled.

9. Under Section 6402(d) of PPACA, the Defendant parent corporations tasked with oversight had 60 days to return Medicare and Medicaid overpayments. Upon information and belief, Defendant parent corporations have failed to return overpayments received for Defendant Costa's fraudulent and medically unnecessary services, thereby intentionally defrauding the federal government and the State of Texas by retaining Medicare and/or Medicaid payments to which they were not entitled.

### **THE PARTIES**

#### **A. Plaintiff-Relator**

10. Plaintiff-Relator Derrick Nguyen, M.D. ("Dr. Nguyen" or "Relator") is a citizen of the state of Texas.

11. Relator is a Board-Certified Internal Medicine Physician and a Board-Certified Medical Oncology Physician.

12. Relator's extensive education was completed at institutions throughout the states of Texas and New Mexico; he holds a Medical Degree from the University of Texas Health Science Center in San Antonio, completed his residency at the University of New Mexico Health Sciences Center in Albuquerque, and did his fellowship at the University of Texas Health Science Center in San Antonio.

13. Relator was medically licensed in New Mexico and has been licensed to practice medicine in Texas for nearly 10 years.

14. Relator has been published in five medical publications, has been the principal investigator in 22 clinical trials, and has sub-investigated six clinical trials.

15. Relator has personal knowledge that Defendant Costa knowingly filed fraudulent claims that did not comply with CMS guidelines.

16. Relator is aware that Defendant parent corporations knew or should have known of the overpayments through their oversight responsibility.

17. Relator knows of many instances of patient complications and harm as a result of Defendant Costa's fraudulent and unethical activity.

18. Relator discovered these violations during his employment with TOPA.

19. Relator worked for TOPA from 2009 until October 2015.

20. Relator became aware of Defendants' fraudulent activity through the scope of his employment.

## **B. Defendants**

21. Defendant McKesson Corporation is a supplier of medical supplies,

pharmaceuticals, and health plans with its corporate headquarters located at One Post Street, San Francisco, CA 94104. McKesson owns and manages the US Oncology Network. It also provides Electronic Medical Record System known as IKnowMed for US Oncology Network (including TOPA). McKesson collaborates with US Oncology Network (including TOPA), Medicare, Medicaid, and private insurance companies to provide treatment guidelines for the US Oncology Network (including TOPA).

22. Defendant US Oncology, Inc., d/b/a US Oncology Network, operates a network of integrated community-based oncology practices that provides cancer care services in the United States. Its corporate office is located at 10101 Woodloch Forest, The Woodlands, Texas 77380. US Oncology, Inc. operates as a subsidiary of McKesson Corporation. Specifically, US Oncology Network is supported, owned and managed by McKesson Specialty Health, a division of McKesson Corporation. US Oncology Network is the largest community-based practice in the United States. It is a physician led organization that employs and manages over 1,000 physicians at more than 350 sites in 19 states.

23. Defendant Texas Oncology, P.A. (“TOPA”) is a private Texas professional association with its corporate office located at 12221 Merit Drive, Suite 500, Dallas, TX 75251. It is a practice within The US Oncology Network. TOPA is a physician led network that employs and manages more than 400 physicians within Texas.

24. Defendant Dennis J. Costa, M.D. (“Defendant Costa”) is a physician duly licensed to practice internal medicine, hematology, and oncology in the State of Texas. At all relevant times, Defendant Costa has been a shareholder in TOPA and has practiced at TOPA’s Flower Mound and Lewisville, TX locations. At all relevant times, Defendant Costa has treated Medicare and Medicaid beneficiaries.

25. Relator frequently refers to other Oncologists and supervisors in this Complaint. They include:

26. Barry Brooks, MD: Vice Chairman of the Pharmacy and Therapeutics Committee and Chairman of the Contracting Subcommittee for US Oncology Network.

27. Bruce Broussard: Former CEO, President, CFO, Chairman of the Board at McKesson until 2011.

28. Allison Eisenmann, Pharm.: Pharmacist for Texas Oncology with Defendant Costa's Practice.

29. Christine Hall: Executive Director of Revenue Cycle Operations at Texas Oncology; previous Director of Revenue Cycle for US Oncology.

30. John Hammergren: Chairman, President, and CEO of McKesson.

31. Chris Henderson: Executive Director for Payer and Public Relations at Texas Oncology.

32. Russell Hoverman, Pharm: Medical Director of Innovent Oncology for US Oncology and Texas Oncology; Vice President of Quality Programs for Texas Oncology.

33. Kirk Kaminsky: Current President of US Oncology; former Senior Vice President of McKesson Specialty Health Operations; former Senior Vice President of Strategy and Business Development for McKesson Specialty Health located in Woodlands, Texas.

34. Kathy Kreamer: Practice Manager for Texas Oncology with Defendant Costa's Practice.

35. Nick Loporcaro: President of McKesson Specialty Health located in Woodlands, Texas.

36. Glenn Noble: Executive Director for Northeast Texas Oncology and Defendant

Costa's practice; former Executive Director for US Oncology Practices in Chicago.

37. Michael Park, MD: Partner of Defendant Costa who saw patients that, upon information and belief, were overtreated by Defendant Costa and signed off on their treatments.

38. Anil Bhogaraju, MD: Partner of Defendant Costa who saw patients that, upon information and belief, were overtreated by Defendant Costa and signed off on their treatments.

39. Steve Paulson, MD: President & Chairman of Board for Texas Oncology.

40. Jim Schwartz: Executive Director of Pharmacy Services for Texas Oncology.

41. J. Ernest Sims - Executive Director of Texas Oncology.

42. Kona Vinson: Business Manager for Texas Oncology with Defendant Costa's Practice.

43. Michael Vogel - State Controller for Texas Oncology; CBO controller for US Oncology.

44. Allen Weikel: Senior Vice President of Regional Operations at McKesson Specialty Health; former Executive Director for Texas Oncology with Defendant Costa's practice.

45. Charles White, MD: Medical Director of Texas Oncology; Vice President of Texas Oncology since 1988; Board of Directors for Texas Oncology since 1986; on Executive Committee for Texas Oncology; member of US Oncology Network's National Policy Board and Executive Committee of Pharmacy and Therapeutics.

46. Lalan Wilfong, MD: Medical Director Quality Programs for Texas Oncology; Electronic Medical Record and Pharmacy & Therapeutics Committee for US Oncology.

47. Cathleen Williams: Business Manager for Texas Oncology with Defendant Costa's Practice.

**JURISDICTION AND VENUE**

48. This Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331 and 1345.

49. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and/or 28 U.S.C. § 1391(b) because Defendants transact business in this District and because, on information and belief, one or more of the acts committed by Defendants and proscribed by 31 U.S.C. § 3729 *et seq.* occurred in this District.

50. This Court has personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because Defendants transact business in this District and because Defendants submitted false or fraudulent claims directly or indirectly to the federal government in this district.

51. Relator has direct and independent knowledge on which the allegations are based, is an original source of this information to the United States and the State of Texas, and voluntarily provided the information to the United States and the State of Texas before filing his original complaint on November 25, 2015.

52. Relator is an original source as defined by 31 U.S.C. § 3730(e)(4)(B).

**FILING UNDER SEAL**

53. Pursuant to 31 U.S.C. § 3730(b)(2), this Complaint must be filed *in camera* and remain under seal for a period of at least sixty days and shall not be served on Defendants until the Court so orders. The Complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene and proceed with the action within sixty days after the Government receives the Complaint.

## **FEDERAL AND STATE-FUNDED HEALTH CARE PROGRAMS**

### **A. Medicare**

54. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities. Medicare Part A provides hospital insurance for eligible individuals. 42 U.S.C. §1395c-1395i.

55. Medicare Part B is a voluntary subscription program of supplementary medical insurance covering items and services other than hospitalization expenses. 42 U.S.C. § 1395k(a)(2)(B).

56. Medicare covers chemotherapy for cancer patients who are hospital inpatients and outpatients as well as patients in a doctor's office or freestanding clinic. *See* Medicare.gov, "Your Medicare Coverage: Chemotherapy," available at <https://www.medicare.gov/coverage/chemotherapy.html> (last accessed Sept. 24, 2015).

57. To be covered, drugs – including those used in the course of chemotherapy – “must be safe and effective and otherwise reasonable and necessary.” CMS, *Medicare Benefit Policy Manual*, Pub. 100-02 (2015), Ch. 15 § 50.4.1 (hereinafter “MBPM”). Medicare will not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y(a)(1)(A); MBPM, Ch. 16 § 20.

### **B. Medicaid**

58. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law. Medicaid pays for items and services pursuant to plans developed by the states and approved by the United States Department of Health and Human

Services (“HHS”) through the Centers for Medicare & Medicaid Services (“CMS”). 42 U.S.C. § 1396a(a)-(b). States pay health care providers, including physicians, according to established rates, and the federal government then pays a statutorily established share of “the total amount expended ... as medical assistance under the State plan.” 42 U.S.C. § 1396b(a)(1).

59. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees, and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the State. Among the rules and regulations that enrolled providers agree to follow are to: (1) bill only for covered services that are medically necessary; (2) neither bill for any services or items that were not performed or delivered in accordance with applicable policies nor submit false or inaccurate information relating to provider costs or services; (3) not engage in any act or omission that constitutes or results in over-utilization of services; (4) be fully licensed and/or certified under the applicable state and federal laws to perform the services provided to recipients; (5) comply with state and federal statutes, policies, and regulations applicable to the Medicare and Medicaid programs; (6) not engage in any illegal activities related to the furnishing of services to recipients.

60. At all relevant times, the United States has provided funds to Texas for its Medicaid programs, which Texas administers through the Texas Health and Human Services Commission (“HHSC”), and HHSC, through CMS, has ensured that Texas has complied with minimum federal standards in its administration of the Medicaid programs.

61. Texas Medicaid covers chemotherapy for cancer patients who are hospital inpatients and outpatients, as well as patients in a doctor’s office or freestanding clinic. *See* Texas Medicaid Provider Procedures Manual, “Hospital Services Handbook,” Vol. 2, § 2.3.3.2

(2011), available at [http://www.tmhp.com/tmppm/2011/vol2\\_hospital\\_services\\_handbook.pdf](http://www.tmhp.com/tmppm/2011/vol2_hospital_services_handbook.pdf) (last accessed Sept. 24, 2015) (hereinafter “TMPPM”); *See also* HHSC, Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, “Chemotherapy,” § 8.2.18, available at <http://www.tmhp.com/HTMLmanuals/TMPPM/2011/2011TMPPM-30-120.html> (last accessed Sept. 24, 2015) (listing chemotherapy infusion procedure codes).

62. HHSC does not cover drugs or services that are “not reasonable and necessary for diagnosis or treatment.” TMPPM, Vo. 1, § 1.11 (2014), available at [http://www.tmhp.com/TMHP\\_File\\_Library/Provider\\_Manuals/TMPPM/2014/TMPPM\\_August\\_2014.pdf](http://www.tmhp.com/TMHP_File_Library/Provider_Manuals/TMPPM/2014/TMPPM_August_2014.pdf) (last accessed Dec. 13, 2016).

### **APPLICABLE FEDERAL LAWS AND REGULATIONS**

#### **A. The United States False Claims Act**

63. Under the FCA, 31 U.S.C. § 3729(a)(1)(A), it is a violation of federal law to knowingly present or cause to be presented a fraudulent claim to the United States. For every violation, the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of \$5,500 to \$11,000 per claim for claims made on or after September 29, 1999.

64. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes it a violation of federal law to knowingly make, use, or cause to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. The United States may recover three times the amount of the damages that the Government sustains and a civil monetary penalty of \$5,500 to \$11,000 per claim for claims made on or after September 29, 1999.

65. The FCA, 31 U.S.C. § 3729(a)(1)(C), prohibits conspiring to commit a violation of the FCA. For every violation, the United States may recover three times the amount of the

damages the Government sustains and a civil monetary penalty between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

66. The FCA, 31 U.S.C. § 3729(a)(1)(G), makes it a violation of federal law to knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government. It further makes it a violation of federal law to knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government.

67. The FCA defines a “claim” to include any request or demand, whether under a contract or otherwise, for money or property, which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested, 31 U.S.C. § 3729(b)(2).

68. The FCA, 31 U.S.C. § 3729(b)(1) provides that “‘knowing’ and ‘knowingly’— (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.”

69. The FCA, 31 U.S.C. § 3729(b)(4) provides that “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” A violation of the Anti-Kickback Statute or the Stark Act renders resulting claims to Medicare false or fraudulent in violation of the FCA. Moreover, the Patient Protection and Affordable Care Act, Publ. L. No. 111-148, 124 Sta. 119 § 6402(f)(1) (2010), described *infra*,

makes clear violations of the AKS or the Stark Act give rise to liability under the FCA.

**B. The Texas Medicaid Fraud Prevention Act (“TMFPA”)**

70. The State of Texas Medicaid Fraud Prevention Act § 36.002(1) prohibits knowingly making or causing to be made a false statement or misrepresentation of a material fact to permit receipt of a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

71. The State of Texas Medicaid Fraud Prevention Act § 36.002(2) prohibits knowingly concealing or failing to disclose information that permits receipt of a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

72. The State of Texas Medicaid Fraud Prevention Act § 36.002(7)(B) prohibits knowingly making or causing to be made a claim under the Medicaid program for a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the healthcare industry.

73. The State of Texas Medicaid Fraud Prevention Act § 36.002(12) prohibits knowingly making or using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to this state under the Medicaid program.

74. The State of Texas Medicaid Fraud Prevention Act § 36.002(13) prohibits knowingly engaging in conduct that constitutes a violation under Section 32.039(b).

**C. The Patient Protection and Affordable Care Act (“PPACA”)**

75. The Patient Protection and Affordable Care Act (“PPACA”) Section 6402,

Enhanced Medicare and Medicaid Program Integrity Provisions, amended Part A of Title XI of the Social Security Act ( 42 U.S.C. § 1301 et seq.).

76. Section 6402(d) of PPACA provides:

(d) Reporting and Returning of Overpayments –

(1) IN GENERAL – If a person has received an overpayment, the person shall –

(A) report and return the overpayment to the Secretary of State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS - An overpayment must be reported and returned under paragraph (1) by the later of –

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

(3) “ENFORCEMENT” – Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b )(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS - In this subsection:

(5) KNOWING AND KNOWINGLY - The terms 'knowing' and 'knowingly' have the meaning given those in section 3 729(b) of title 31, United States Code.

(6) OVERPAYMENT-The term 'overpayment' means any funds that a person received or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

**DEFENDANTS' CONDUCT IN VIOLATION OF THE FCA AND TMFPA**

**A. Background on Drugs, Drug Indications and Reimbursement Rates<sup>1</sup>**

**1. Rituximab**

77. Rituximab is reimbursed at up to \$9,000.00 per dose.

78. Rituximab (brand name "Rituxuan") is used to treat cancer and immune system disorders by targeting and destroying abnormal cells directly involved in the human immune response.

79. Rituximab is used in the treatment of Non-Hodgkin's Lymphomas (or "NHLs"), including Diffuse large B cell lymphoma ("DLBCL"), Extranodal marginal zone B cell lymphoma of mucosa associated lymphoid tissue ("MALT"), Follicular lymphoma ("FL"), and Mantle cell lymphoma ("MCL").

80. Rituximab is also used as a maintenance therapy drug. Maintenance therapy refers to the prolonged administration of agents with low toxicity profiles in an attempt to prevent progression of disease.

81. Although maintenance therapy is designed to potentially decrease the risk of recurrence or progression, a decision regarding the use of maintenance therapy on an individual patient must take into consideration both the potential benefit and harm. Maintenance therapy does not guarantee against risk of recurrence or progression.

82. Pursuant to established guidelines, physicians should not administer Rituximab to a patient more than 12 to 16 times.

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<sup>1</sup> Several trials have investigated the use of maintenance rituximab after chemoimmunotherapy, after immunotherapy alone, and after chemotherapy alone for previously untreated NHL. For ease of reading, this section omits citations to the relevant medical literature, Relator attaches as Exhibit 1, a list of supporting medical literature relevant to both the rituximab and IVIG standards. In addition, Dr. Nguyen is a board-certified medical oncologist who can testify to the guidelines described herein.

83. In concert with National Comprehensive Cancer Network (NCCN), the Federal Drug Administration (FDA) indication, and UpToDate literature, maintenance therapy should not exceed two years in the majority of previously untreated Non-Hodgkin's Lymphomas.

84. No published data exists regarding the safety or efficacy of administering maintenance Rituximab more frequently than every two months for a total of two years (not to exceed 12 doses) or administering Rituximab beyond four consecutive weeks every six months in two years (not to exceed 16 doses) for previously untreated NHL.

85. Rituximab imposes a risk of Hepatitis B reactivation among patients positive for Hepatitis B surface antigens or antibodies.

86. The standard of care requires physicians to adhere to established guidelines because prolonged use of Rituximab may result in side effects, including cardiovascular, neurologic, infectious, dermatologic, gastrointestinal, hematologic, respiratory, endocrine, anaphylaxis, fatal infusion reactions, and death.

87. The standard of care for oncologists requires that decision and treatment algorithms for maintenance Rituximab should be evidence-based. There are evidence-based NCCN guidelines and FDA approved indications for the dosing and duration of Rituximab treatments.

88. Upon information and belief, McKesson, US Oncology Network, and Texas Oncology base treatment algorithms, including dosing and duration of Rituximab (and all other chemotherapies), on the NCCN guidelines. McKesson calls said treatment guidelines "Clear Value Plus" and the software it uses, evidence-based "Value Pathways," is "powered by NCCN."

89. There does not exist enough data to suggest that continued maintenance therapy

with Rituximab beyond established guidelines leads to the prevention of disease progression.

**2. Intravenous Immune Globulin**

90. IVIG is reimbursed at up to \$6,000.00 per dose.

91. IVIG therapy is used to treat an array of disorders, including primary and secondary immune deficiency states and a variety of autoimmune and inflammatory disorders.

92. IVIG indications include, but are not limited to states of immunodeficiency, recurrent infections, autoimmune, and inflammatory conditions causing low immunoglobulin levels.

93. IVIG is used as a treatment for patients who have a decreased amount or absence of antibody production in the human immune system.

94. Rituximab causes patients to develop low immunoglobulin levels and thereby predisposes patients to recurrent infections. IVIG can be used to correct the low immunoglobulin levels that are caused by Rituximab.

95. It is Relator's position that unnecessary, potentially harmful, and expensive overtreatment with Rituximab leads to more unnecessary, potentially harmful, and expensive overtreatment with IVIG.

96. Treatment with IVIG is normally given to patients previously treated with chemotherapy regimens in an effort to strengthen the immune systems that may have been compromised.

97. There is no standard protocol mandating the use of IVIG if Rituximab is being prescribed beyond the recommended two-year maintenance in B-cell low grade NHL to reduce infections.

98. Prolonged use of IVIG may result in numerous complications, including

inflammatory reactions, cardiovascular, neurologic, respiratory, gastrointestinal, dermatologic, thromboembolic, hematologic, renal failure, hemolytic anemia, anaphylaxis, fatal infusion reactions, and death.

99. Any of the above-mentioned conditions may lead to organ failure and death.

100. Adverse reactions affect 20 to 50 percent of individuals receiving IVIG.

101. Risk factors include the dose, frequency of infusions, infusion rate, and organ dysfunction.

102. According to the literature, there does not exist enough data to suggest the cost effectiveness of prolonged IVIG treatment and its correlation with the prevention of infection.

**B. Improper and Excessive Treatment Resulting in Patient Harm**

103. As a direct result of Defendants' conduct, many patients, including government health care program beneficiaries, have received excessive and medically unnecessary treatments in violation of federal and state requirements, as defined above.

104. Relator became aware of Defendants' fraudulent conduct on or around June 22, 2015.

105. Relator reviewed records of patients treated by Defendant Costa over a six-week period from June 22, 2015, to August 5, 2015.

106. In that six-week period, Relator found evidence of twenty patients that had been improperly and excessively treated by Defendant Costa. Based on Relator's observation and best estimates, Defendant Costa has treated up to **2,500** patients excessively and unethically during his 25 years of practice.

107. Upon information and belief, for each Rituximab or IVIG treatment, Dr. Costa collects 70% profit from the administration of such medications, while Texas Oncology, US

Oncology Network, and McKesson benefit from the remaining 30% profit from such administration of medications.

108. Upon information and belief, Dr. Costa, Texas Oncology, US Oncology Network and McKesson are financially incentivized and rewarded for overtreatment (and potential patient harm or death) with excessive and unnecessary Rituximab and IVIG therapies.

109. Upon information and belief, in all of Defendant Costa's Rituximab treatments, he administers weekly Rituximab for 6 consecutive weeks (every 6 months).

110. There is no such FDA approved indication or NCCN guideline for that excessive frequency of Rituximab.

111. The only FDA approved indications are every 2 months, every 3 months, or weekly Rituximab for 4 consecutive weeks (every 6 months) for 2 years in previously untreated NHL.

112. By giving such non-FDA and non-NCCN guideline treatments too frequently, Defendant Costa places patients at greater risk for infection and death, without any evidence of benefit for the patient.

113. Additionally, upon information and belief, Defendant Costa is reimbursed more for too frequent, excessive, and unnecessary therapies.

114. By way of example, Defendant Costa provided improper and excessive treatment to the following twelve Medicare beneficiaries:

1. **Patient 1** is a 53-year-old female with Stage 3-A Diffuse Large B-Cell Lymphoma (DLBCL) diagnosed 05/2009. She received R-CHOP chemotherapy for 8 cycles. She achieved complete remission and was cured of lymphoma by 11/2009. For DLBCL, any dose of Rituximab beyond initial induction chemotherapy is considered excessive. There

is no FDA approved indication or NCCN guideline for maintenance therapy in DLBCL treatment. Despite being cured of her disease in 2009, Patient 1 received an additional 63 doses of Rituximab treatments (8 + 63 Rituximab therapies = 71 treatments) from 2009 to 2015. Upon information and belief, Defendant Costa planned indefinite Rituximab therapy for this patient. **(\$6,746.04 for a 700 mg Rituximab dose) x (63 excessive treatments) = \$424,998 of overtreatment with Rituximab.**

2. **Patient 2** is a 69-year-old female with Stage 2-B DLBCL diagnosed 05/2006. She received R-CHOP chemotherapy for 8 cycles and completed treatment in 09/2006. She achieved complete remission and was cured of lymphoma by 09/2006. For DLBCL, any dose of Rituximab beyond initial induction chemotherapy is considered excessive. There is no FDA approved indication or NCCN guideline for maintenance therapy in DLBCL treatment. However, Defendant Costa administered an extra 100 treatments of Rituximab from 3/26/2008 to most recently 8/5/2015. Additionally, Defendant Costa has administered 38 treatments of IVIG from 8/1/2012 to 7/29/2015. Upon information and belief, Defendant Costa planned indefinite Rituximab and IVIG therapy. **(\$7709.76 for a 800 mg Rituximab dose) x (100 excessive treatments) = \$770,976 of overtreatment with Rituximab. (\$5590 for a 35 gm dose of Octagam IVIG) x (38 excessive treatments) = \$212,427.60 of overtreatment with IVIG.**

3. **Patient 3** is a 65-year-old female with Stage 4-A Mantle Cell Lymphoma diagnosed 10/2005. She has been in complete remission since 04/2006. Despite being in remission since 2006, Defendant Costa continued Rituximab for an additional 93 treatments from 12/2007 to 8/5/2015. He administered IVIG unnecessarily 59 times from 12/9/2010 to 7/15/2015. While it is acceptable that Rituximab maintenance be administered for such a

long duration in Mantle Cell Lymphoma, Defendant Costa used excessive, improper dosing, and too frequent dosing for maintenance therapy of Rituximab. He administered Rituximab for 6 consecutive weeks (every 6 months). At most, Rituximab can be administered weekly for 4 weeks straight (every 6 months). The FDA-approved indication is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months). Instead, Defendant Costa created his own weekly schedule. Since Week 5 and 6 of each of his Rituximab treatments are unnecessary (and not FDA approved, nor recommended by NCCN guidelines), one third of all treatments are unnecessary and lacking any evidence based guidelines. Upon information and belief, Defendant Costa planned indefinite Rituximab and IVIG therapy for this patient. **(\$5782 for a 600 mg Rituximab dose) x (30 excessive treatments) = \$173,469 of overtreatment with Rituximab. (\$3009 for a 30 gm dose of Flebogam IVIG) x (59 excessive treatments) = \$178,161.12 of overtreatment with IVIG.**

4. **Patient 4** is a 93-year-old male with Stage 4-A Lymphoplasmacytic Lymphoma. He has been in complete remission since 2010. He received a total of 77 doses of Rituximab treatments from 2010 to 2015. He administered Rituximab for 6 consecutive weeks (every 6 months). At most, Rituximab can be administered weekly for 4 weeks straight (every 6 months). The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months) for a total of 2 years in this previously untreated NHL patient. Due to excessive and unnecessary Rituximab, Patient 4 received 3 unnecessary IVIG treatments starting 5/13/2015. Upon information and belief, Defendant Costa planned indefinite Rituximab and IVIG therapy. **(\$8673.48 for a 900 mg Rituximab dose) x (77 excessive**

**treatments) = \$667,857 of overtreatment with Rituximab. (\$3322.08 for a 20 gm IVIG dose) x (3 excessive treatments) = \$9,966.24 of overtreatment with IVIG.**

5. **Patient 5** is an 85-year-old male with Stage 2-B DLBCL diagnosed 12/2005. He has been cured since 2006. Despite being cured since 2006, he received an additional 89 doses of maintenance Rituximab from 12/2007 to 6/3/2015. For DLBCL, any dose of Rituximab beyond initial induction chemotherapy is considered excessive. There is no FDA approved indication or NCCN guideline for maintenance therapy in DLBCL treatment. Upon information and belief, Defendant Costa plans indefinite Rituximab therapy. **(\$7709.72 for a 800 mg Rituximab dose) x (89 excessive treatments) = \$686,165.08 of overtreatment with Rituximab.**
6. **Patient 6** is a 44-year-old female with Stage IV-B MALT lymphoma NHL (Non-Hodgkin's Lymphoma) diagnosed 02/2011. She received R-CVP x 10 cycles from 03/2011 to 10/2011. She has been in complete remission since 12/2011, but received 44 additional doses of Rituximab from 3/21/2011 to 8/10/2015. She received a total of 54 cycles of Rituximab, of which 28 doses were excessive. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for a total of 2 years in this previously untreated NHL patient. Upon information and belief, Defendant Costa planned indefinite Rituximab therapy for this patient. **(\$7709.76 for a 800 mg Rituximab dose) x (28 excessive treatments) = \$215,873.28 for Rituximab.**
7. **Patient 7** is an 81-year-old male with DLBCL diagnosed in 1994. He was in remission until he developed a Follicular Lymphoma (indolent NHL) in 2002. Despite going into

complete remission after treatment for follicular lymphoma since 2002, Defendant Costa administered an additional 87 Rituximab treatments from 11/2007 to 5/20/2015. From 2002 to 2007, records are not available. Relator believes that from 2002 to 2007, approximately 60 to 70 additional Rituximab doses were administered. From 2007 to 2015, 88 Rituximab doses were administered. It is estimated Patient 7 received about 150 doses of Rituximab total. Patient 7 received 80 unnecessary doses of IVIG from 2009 to 7/22/15, with indefinite plans for continuation of IVIG. For DLBCL, any dose of Rituximab beyond initial induction chemotherapy is considered excessive. There is no FDA approved indication or NCCN guideline for maintenance therapy in DLBCL treatment. Upon information and belief, Defendant Costa planned indefinite Rituximab and IVIG therapy for this patient. **(\$7709.76 for a 800 mg Rituximab dose) x (88 excessive treatments) = \$617,780 for Rituximab. Possibly 70 unaccounted treatments 2003-2006 (\$7709.76 for a 800 mg Rituximab dose) x 70 = \$539,683 of overtreatment with Rituximab. \$3737.60 at 42 gm Carimune IVIG dose) x (80 excessive treatments) = 379,008 of overtreatment with IVIG**

8. **Patient 8** is a 77-year-old male with Stage 4-A Lymphoplasmacytic Lymphoma (Non-Hodgkin's Lymphoma) diagnosed 11/2007. Despite being in complete remission since 2008, Defendant Costa administered 101 additional Rituximab treatments from 2007 to 2015. Defendant Costa administered 87 excessive doses of Rituximab. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for a total of 2 years in this previously untreated NHL patient. Upon information and belief, Defendant Costa planned to administer Rituximab indefinitely. Upon information and belief, Defendant Costa

planned indefinite Rituximab therapy for this patient. **(\$7709.76 for a 800 mg dose of Rituximab) x (87 excessive treatments) = \$670,749.20 of overtreatment with Rituximab.**

9. **Patient 9** is a 63-year-old male with Stage 4-A Marginal Zone Lymphoma (Non-Hodgkin's Lymphoma) diagnosed in 04/2009. Despite achieving complete remission in 03/2010, he received an additional 73 excessive Rituximab maintenance doses from 2009 to 2015. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for a total of 2 years in this previously untreated NHL patient. Upon information and belief, Defendant Costa planned indefinite Rituximab therapy for this patient. **(\$8673.48 for a 900 mg Rituximab dose) x (73 excessive treatments) = 633,164.04 of overtreatment with Rituximab.**

10. **Patient 10** is an 84-year-old female with Stage 3-A Follicular Lymphoma (Non-Hodgkin's Lymphoma) diagnosed in 05/2009. She received R-CHOP chemotherapy x 8 cycles for induction therapy. She has been in complete remission since 2010. She received 12 additional doses of Rituximab with her former physician Dr. Mahmood from 05/2009 through 04/2011. Then, Defendant Costa administered an additional 38 Rituximab treatments from 2011 to 2015. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for a total of 2 years in this previously untreated NHL patient. Upon information and belief, Defendant Costa planned to administer Rituximab indefinitely for this patient. **(\$6746.04 for a 700 mg Rituximab dose) x (34 excessive treatments) = \$229,365.36 of overtreatment with Rituximab.**

11. **Patient 11** is a 67-year-old female with Stage 3-A MALT Lymphoma (NHL) diagnosed 06/2010. She received induction chemotherapy with R-CVP chemotherapy x 8 cycles. She achieved complete remission by 01/2011. She received an additional 49 doses of Rituximab maintenance from 8/31/2011 to 8/10/2015. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for a total of 2 years in this previously untreated NHL patient. Upon information and belief, Defendant Costa planned indefinite Rituximab therapy for this patient. **(\$6746.09 for a 700 mg Rituximab dose) x (33 excessive treatments) = \$222,620.97 of overtreatment with Rituximab.**
12. **Patient 12** is a 66-year-old male with Stage IV-B Mantle Cell Lymphoma diagnosed 01/2011. He received Rituximab plus HyperCVAD chemotherapy upfront and had a bone marrow transplant in 10/2011. After the bone marrow biopsy performed 05/2012, he was in complete remission. Since diagnosis, he received 8 Rituximab initial treatments with an additional 46 more cycles of Rituximab with last treatment on 3/12/2015 (total of 54 Rituximab treatments). While it is acceptable that Rituximab maintenance be administered for such a long duration (from 2011 to 2015) in Mantle Cell Lymphoma, Defendant Costa uses excessive and improper doses for maintenance therapy of Rituximab. For all of these Rituximab treatments, Defendant Costa's doses at 500 mg/m<sup>2</sup>. The correct dose should be 375 mg/m<sup>2</sup>. The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for this previously untreated NHL patient. Instead, Defendant Costa creates his own weekly schedule. Since week 5 and 6 of each of his Rituximab treatments are unnecessary, one third of all treatments are unnecessary. Upon information and belief,

Defendant Costa planned indefinite Rituximab therapy for this patient. **Overdosing**  
**Rituximab (500 mg/m<sup>2</sup> vs correct dose of 375 mg/m<sup>2</sup>) x (30 treatments) = \$8,673.48**  
**x 30 x 25% = \$65,051.10 of overtreatment with Rituximab. (\$8673.48 at 900 mg**  
**Rituximab dose) x (15 excessive treatments) = \$130,102.20 of overtreatment with**  
**Rituximab.**

115. Relator reviewed records of patients treated by Defendant Costa over a six-week period from June 22, 2015, to August 5, 2015. In that six-week period, Relator found evidence of 20 patients that had been improperly and excessively treated by Defendant Costa.

116. Upon information and belief, Defendant Costa's excessive use of Rituximab resulted in many of the above patients developing documented complications that resulted in subsequent severe infections and hospitalizations, and Defendant Costa is continuing to administer these medications indefinitely.

117. Upon information and belief, the office visits and procedures associated with Defendant Costa's administration of Rituximab to these patients were also unnecessary. Based on Relator's experiences cross-covering Defendant Costa's patients, Relator believes that Defendant Costa's improper and excessive treatment practices are not limited to NHL, but extend to his treatment of patients with solid tumors as well.

118. Upon information and belief, Defendant Costa's use of IVIG was primarily necessitated by his improper and excessive use of Rituximab. Because the IVIG treatments were themselves unnecessary, Defendant Costa's office visits and procedures associated with his administration of IVIG were unnecessary. The associated procedures include laboratory evaluation, radiological imaging, premedication administration, "Mediport" placement or access, and venous access.

119. Upon information and belief, the above examples represent merely a fraction of the fraudulent conduct resulting in false claims paid by the federal health care programs as a result of Defendant Costa's wrongful conduct.

120. Based on Relator's observation and best estimates, Defendant Costa has treated approximately up to 2,500 patients excessively and unethically during his 25 years of practice.

121. Upon information and belief, Defendant Costa has defrauded the Government of over seven (7) million dollars.

122. By way of example, Defendant Costa's improper and excessive treatment caused patient harm, as described below, to the same twelve Medicare beneficiaries outlined above:

1. **Patient 1** received Rituximab unnecessarily, resulting in low immunoglobulins.

Defendant Costa's notes specifically stated that Patient 1 developed "recurrent yeast and fungal infections." Despite these recurrent infections, Defendant Costa continued to give an additional 63 doses of Rituximab. In addition, Defendant Costa altered patient medical and pathology records to state "DLBCL arose from indolent NHL" in an effort to justify his excessive administration of Rituximab. The pathology records clearly indicate that the DLBCL did not arise from indolent NHL. There is no FDA indication or NCCN guideline for Rituximab maintenance therapy after curative treatment for DLBCL. At most, the FDA approved indication for Rituximab maintenance for indolent previously untreated NHL is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months) for this previously untreated NHL patient. Upon information and belief, Defendant Costa intended to and/or did administer Rituximab therapy indefinitely despite Patient 1 being cured in 2009.

2. **Patient 2** received over 100 treatments of Rituximab, resulting in low immunoglobulins. As a result, unnecessary and excessive use of IVIG was administered in order to raise immunoglobulin levels. Defendant Costa was able to carry this out by altering Patient 2's pathology records in order to justify his excessive administration of Rituximab. In addition, Patient 2 developed life-threatening pneumonia as well as shingles in her right eye due to the excessive administration of Rituximab, despite the patient being cured of disease since 09/2006. In addition, Defendant Costa altered patient medical and pathology records to state "DLBCL arose from indolent NHL" in an effort to justify his excessive administration of Rituximab. The pathology records clearly indicate that the DLBCL did not arise from indolent NHL. There is no FDA indication or NCCN guideline for Rituximab maintenance therapy after curative treatment for DLBCL. Defendant Costa intended to and/or did administer Rituximab therapy indefinitely.
3. **Patient 3** received over 93 excessive treatments of Rituximab despite being in remission since 2006. Defendant Costa uses excessive and improper doses for maintenance therapy of Rituximab. He administered Rituximab weekly for 6 weeks straight (every 6 months). At most, Rituximab can be administered weekly for 4 weeks straight (every 6 months). The FDA approved indication for Rituximab maintenance is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for this previously untreated NHL patient. Since week 5 and 6 of each of his Rituximab treatments are unnecessary, one third of all treatments were unnecessary. The excessive and incorrect dosing of Rituximab resulted in "upper respiratory infections, urinary tract infections", and ultimately the unnecessary administration of IVIG. If Rituximab was prescribed at normal protocol, Patient 3 may have never had these infections and may have never

required IVIG. Defendant Costa intended to and/or did administer Rituximab and IVIG therapy indefinitely.

4. **Patient 4** received over 77 excessive doses of Rituximab from 2010 to 2015. Defendant Costa administers Rituximab treatment every 4 weeks (12 treatments each year) from 2010 to 2015 for a total of 77 Rituximab doses. Defendant Costa knowingly used the wrong and higher dose and frequency of Rituximab (500 mg/m<sup>2</sup>). At most, the FDA approved indication for Rituximab maintenance (375 mg/m<sup>2</sup>) for indolent previously untreated NHL is 4 consecutive weeks (every 6 months), not 6 consecutive weeks (every 6 months), for this previously untreated NHL patient. This resulted in the hospitalization of Patient 4 due to severe pneumonia during 03/2013. Even after Patient 3 recovered from the pneumonia, Defendant Costa resumed Rituximab treatment. Defendant Costa intended to and/or did administer Rituximab and IVIG therapy indefinitely.
5. **Patient 5** developed a right leg vein harvest infection in 07/2010 and severe pneumonia in Spring 2014, requiring hospitalization. Despite these recurrent infections from 2010 to 2014, Defendant Costa continued to give an additional 89 doses of Rituximab. In addition, Defendant Costa altered patient medical and pathology records to state "DLBCL arose from indolent NHL" in an effort to justify his excessive administration of Rituximab. The pathology records clearly indicate that the DLBCL did not arise from indolent NHL. There is no FDA indication or NCCN guideline for Rituximab maintenance therapy after curative treatment for DLBCL. Upon information and belief, Defendant Costa intended to and/or did administer Rituximab therapy indefinitely, despite Patient 5 being cured in 2006.

6. **Patient 6** received 28 excessive doses of Rituximab, despite being in complete remission since 12/2011. Patient 6 was hospitalized for multiple recurrent infections due to the excessive dosing of Rituximab. According to Defendant Costa's notes, in June 2015 Patient 6 had another brief hospitalization for cellulitis of the right lower lateral calf that would not clear up with oral antibiotics. This required Patient 6 to receive IVs in the hospital for multiple days.
7. **Patient 7** became ill numerous times due to the excessive doing of 88 treatments of Rituximab. According to Defendant Costa's notes, Patient 7 developed "bronchitis, chronic sinusitis, and pneumonia" from 2013 to 2014. Defendant Costa's excessive administration of Rituximab led to Patient 7 developing hypogammaglobulinemia, a condition in which the patient is susceptible to infection. This hypogammaglobulinemia justified the administration of IVIG (intravenous immunoglobulins). Rituximab was not necessary in the first place. Therefore, if Rituximab had not been given, then IVIG would not be necessary.
8. **Patient 8** received 87 excessive doses of Rituximab from 2007 to 2015, despite being in complete remission since 2008. This excessive treatment can lead to recurrent infection resulting from hypogammaglobulinemia.
9. **Patient 9** received 73 excessive doses of Rituximab from 2009 to 2015, despite being in complete remission since 03/2010. Defendant Costa stopped Rituximab treatment when Patient 9 no longer has insurance, stating, "This is his off cycle, so he does not receive Rituximab on this visit. We are actually probably going to put it off a little bit on the next visit in 3 months because of insurance issues." This illustrates that Defendant Costa

administered Rituximab to patients only when he knew he would receive reimbursement and hence financial reward and incentive. Patient 9 also became sick due to the excessive administration of Rituximab. In his notes, Defendant Costa recorded that Patient 9 "got a little bit of a rash under both axilla. This is probably fungal, but we are going to have to give him an antibiotic for bronchitis that he has at the moment. We have to give him oral Diflucan." When the patient was insured again, Defendant Costa resumed the Rituximab therapy with indefinite plans for maintenance therapy.

10. **Patient 10** received 34 excessive doses of Rituximab from 2011-2015, despite being in complete remission since 2010. As stated above, excessive administration of Rituximab can lead to a state of hypogammaglobulinemia in which the patient is at increased risk of developing recurrent infections.
11. **Patient 11** received 33 excessive doses of Rituximab from 8/31/2011 to 8/10/2015, despite being in remission since 01/2011. Excessive administration of Rituximab can lead to a state of hypogammaglobulinemia in which the patient is at increased risk of developing recurrent infections.
12. **Patient 12** received excessive and incorrect doses of Rituximab from 01/2011 to 3/12/2015. Defendant Costa administered an excessive 45 extremely high doses of 500 mg/m<sup>2</sup> Rituximab (protocol suggests 375 mg/m<sup>2</sup> of Rituximab for maintenance therapy of Mantle Cell Lymphoma). As a result, Patient 12 developed "recurrent upper respiratory tract infections and urinary tract infections" as documented from Defendant Costa's notes on July 15, 2015.

**C. Parent Corporation Complicit in Fraud**

123. The parent corporations knew or should have known of the fraudulent actions of their subsidiary. As a result, they are wholly liable pursuant to PPACA.

**1. McKesson's Complicity in Defendant Costa's Conduct**

124. Relator is aware that McKesson, by way of providing software and building "Clear Value Plus Pathways powered by NCCN guidelines" for US Oncology Network and Texas Oncology, performed or should have performed reviews and/or audits of TOPA and Defendant Costa.

125. McKesson owns and employs the US Oncology Network's physicians, including Texas Oncology. A direct 30% management fee is taken directly from any physician charges for oversight and management by TOPA, US Oncology Network, and McKesson.

126. McKesson and/or its agents recklessly disregarded evidence of misdiagnosis or improper, unnecessary, and fraudulent treatment of Defendant Costa's patients.

127. IKnowMed ("IKM") is an electronic medical record system utilized by Defendants US Oncology and TOPA.

128. IKM is a product of McKesson Specialty Health developed in conjunction with physicians of US Oncology.

129. IKM provides built-in chemotherapy treatment pathways for physicians to follow. Chemotherapy treatment algorithms for specific diseases are based on the National Comprehensive Cancer Network.

130. When a physician selects a drug like Rituximab in IKM, its use is either "On-Pathway" or "Off-Pathway." On-Pathway refers to treatment recommended by IKM and Off-Pathway refers to a treatment option not recommended by IKM.

131. Every drug order administered by a physician is internally audited, regardless of whether it is considered On-Pathway or Off-Pathway.

132. All pathways are first audited by the business office and local pharmacy. Audits are then sent through corporate Texas Oncology, The US Oncology Network, TOPA, and McKesson. All chemotherapies or drugs such as Rituximab and IVIG are carefully tracked by Defendants McKesson, US Oncology and TOPA.

**2. The US Oncology Network's Complicity in Defendant Costa's Conduct**

133. Relator is aware that US Oncology performed or should have performed reviews and/or audits of TOPA and Defendant Costa.

134. US Oncology and/or its agents recklessly disregarded evidence of misdiagnosis or improper, unnecessary, and fraudulent treatment of Defendant Costa's patients.

135. IKM is an electronic medical record system utilized by US Oncology and TOPA.

136. IKM is a product of McKesson Specialty Health developed in conjunction with physicians of US Oncology.

137. Every drug order administered through IKM by a physician is internally audited.

138. All pathways are first audited by the business office and local pharmacy. Audits are then sent through TOPA, US Oncology, and McKesson.

**3. TOPA's Complicity in Defendant Costa's Conduct**

139. At all relevant times, TOPA used IKM, an electronic medical record management system ("EMRMS"), that uses pre-defined medicine "pathways" that assist TOPA physicians in drug selection and treatment duration.

140. TOPA's EMRMS provides suggested treatment algorithms based upon national

guidelines such as TOPA Pathways, The National Comprehensive Cancer Network, the Journal of Clinical Oncology, or UpToDate.

141. When a TOPA physician selects a drug like Rituximab in TOPA's EMRMS, its use is either "On-Pathway" or "Off-Pathway."

142. Every drug order administered by a physician is internally audited, regardless of whether it is considered On-Pathway or Off-Pathway.

143. The order goes through an internal audit with both the business office and the pharmacy. The business office then obtains approval from the insurance company.

144. The pharmacy is tasked with ensuring that Rituximab is being administered correctly and in alignment with McKesson, US Oncology Network, and Texas Oncology guidelines which are based directly on National Cancer Comprehensive Network (NCCN) guidelines.

145. If Rituximab is ordered incorrectly or excessively, it must go through practice management, other physicians, the pharmacist, the business department, and other internal audits.

146. The pharmacist must double check the approval with another physician within the practice and have the physician sign off on the excessive doses of Rituximab.

147. If the reviewing physician agrees with the Off-Pathway use, he or she signs a form known as the "Pathway Exception Form." Once the reviewing physician signs the Pathway Exception Form, the drug may be used as Off-Pathway.

148. Based on Relator's experience, TOPA's use of the Pathway Exception Form was a perfunctory process that provided limited actual regulation of medication administration.

149. The excessive dosing of the drug is thereafter sent for further analysis and

auditing at the central TOPA headquarter facilities.

150. Dr. Jim Schwartz (TOPA Pharmacy Director) and Dr. Russell Hoverman (Vice President of Quality Programs for TOPA and Medical Director for Managed Care for US Oncology Networks) analyze and audit the treatment patterns. They determine whether excessive drug therapy is administered.

151. Additionally, Dr. Jim Schwartz and Dr. Russel Hoverman review Pathway Exception Forms to determine whether TOPA physicians are complying with TOPA'S EMRMS-recommended pathways and decide whether requested Off-Pathway regimens are appropriate.

152. If TOPA's Pharmacy Director and Vice President of Quality Programs determine that a physician consistently fails to comply with TOPA pathways or fails to justify his or her Off-Pathway drug administration, they will directly contact either the physician ordering the drug or the local pharmacist in charge of authorizing the drug for the ordering physician.

153. Additionally, Dr. Lalan Wilfong (Medical Director of Quality Programs for Texas Oncology and committee member for Electronic Medical Record/Pharmacy & Therapeutics for US Oncology Network) audits physicians who do not comply with pathways.

154. All of the actions and approvals of Dr. Schwartz and Dr. Hoverman must be evaluated by Dr. Steven Roy Paulson (President and Chairman of the Board for TOPA).

155. Defendant Costa told Relator more than once that TOPA's Vice President of Quality Programs Dr. Russell Hoverman approached him about his Off-Pathway use of Rituximab, but did not taken any action.

156. Dr. Russell Hoverman and Dr. Schwartz directly report Dr. Barry Brooks (Vice

Chairman of the Pharmacy and Therapeutics Committee), J. Ernest Sims (Executive Director of Texas Oncology), Allen Weikel (Senior Vice President of Regional Operations at McKesson Specialty Health; former Executive Director for Texas Oncology with Defendant Costa's practice), Dr. Charles White (Medical Director of Texas Oncology; Vice President of Texas Oncology since 1988; Board of Directors for Texas Oncology since 1986; on Executive Committee for Texas Oncology; member of US Oncology Network's National Policy Board and Executive Committee of Pharmacy and Therapeutics), Glenn Noble (Executive Director for Northeast Texas Oncology and Defendant Costa's practice; former Executive Director for US Oncology Practices in Chicago), and Dr. Steven Paulson (President and Chairman of the Board for TOPA).

157. Dr. Steven Paulson reports directly to the executives at US Oncology Network and McKesson Corporation, including Bruce Broussard (Former CEO, President, CFO, Chairman of the Board at McKesson until 2011), Nick Loporcaro (President of McKesson Specialty Health located in Woodlands, Texas), Kirk Kaminsky (current President of US Oncology; former Senior Vice President of McKesson Specialty Health Operations; former Senior Vice President of Strategy and Business Development for McKesson Specialty Health located in The Woodlands, Texas), and John Hammergren (Chairman, President, and CEO of McKesson).

158. Defendants TOPA, US Oncology Network, and McKesson therefore knowingly approved of Defendant Costa's improper and excessive treatment practices or acted in reckless disregard of those practices.

159. Additionally, Relator approached practice manager Kathy Kreamer, inquiring as to how the excessive doses of Rituximab were approved. Upon information and belief, Kathy

Kreamer told Relator that “more charges are good for the company” and instructed Relator not to ask questions.

160. Kathy Kreamer decides whether the drug should be administered and approved by the aforementioned checkpoints.

**D. False Claims and the Government Damages**

161. At all relevant times, Defendants have had numerous patients who are beneficiaries of the government health programs described above.

162. At all relevant times, Defendants knowingly and willfully billed the above government health programs, and further knowingly and willfully failed to reimburse the above government health programs, for drugs and services that did not meet Medicare and Medicaid billing requirements.

163. At all relevant times, Defendants knowingly concealed and continues to conceal their obligation to pay or transmit money to the United States and the State of Texas.

164. TOPA’s lack of appropriate supervision and medical negligence have resulted in substandard care, patient harm, and governmental fraud.

165. The United States, through its carriers and intermediaries, has made payments to TOPA and has been damaged in an amount to be determined. The United States is entitled to treble its actual damages and to civil penalties in the amount of \$5,500 to \$11,000 for each of the false claims submitted.

166. Upon information and belief, Relator believes that, as a result of Defendant Costa’s wrongful conduct, he may have defrauded the Government and state of Texas of over **\$7,000,000.**

167. The State of Texas, through its carriers and intermediaries, has made payments

to TOPA and has been damaged in an amount to be determined. The State of Texas is entitled to treble its actual damages and to civil penalties in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

**COUNT I**

**Violation of 31 U.S.C. §3729(a)(1)(A)**

168. Relator alleges and incorporates by reference all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

169. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, false and fraudulent claims for payment or approval to the United States – *i.e.*, the foregoing false and fraudulent claims for payments from the government health programs described above – in violation of 31 U.S.C. § 3729(a)(1)(A)).

170. The false and fraudulent claims were presented with Defendants' actual knowledge of their falsity or with reckless disregard or deliberate ignorance of whether or not they were false.

171. Specifically, Defendants submitted claims for payment to the Medicare and Medicaid programs for services that were not medically necessary.

172. The United States relied on these false and fraudulent claims, was ignorant of the truth regarding these claims, and would not have paid Defendants for these false and fraudulent claims had it known the falsity of said claims by Defendants.

173. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act in an amount to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each such violation of the False Claims Act.

**COUNT II**

**Violation of 31 U.S.C. §3729(a)(1)(B)**

174. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

175. In performing the acts described above, Defendants, through their own acts or through the acts of their officers, knowingly and/or recklessly made, used, or caused to be made or used, and continue to make, use, and cause to be made or used, a false record or statement material to a false or fraudulent claim in violation of 31 U.S.C. §3729(a)(1)(B).

176. Defendants' materially false records or false statements are set forth above and include, but are not limited to, false electronic claims submitted to the government health programs, false certifications of the truthfulness and accuracy of claims submitted, and the provision of drugs and therapies to beneficiaries that were not medically necessary in order to get false or fraudulent Medicare and Medicaid claims paid or approved by the United States.

177. As a direct and proximate result of these materially false records or false statements and the related false or fraudulent claims made by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act in an amount to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each such violation of the False Claims Act.

**COUNT III**

**Violation of 31 U.S.C. §3729(a)(1)(G)**

178. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

179. In performing the acts above, Defendants knowingly and/or recklessly made,

used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money to the Government and knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money to the Government in violation of 31 U.S.C. § 3729(a)(1)(G).

180. Specifically, Defendants unlawfully retained and failed to return the overpayments they received as a result of the false and fraudulent billings submitted to Medicare.

181. As a direct and proximate result of the above conduct by Defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act of an amount to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation of the False Claims Act.

#### **COUNT IV**

##### **Violation of Tex. Hum. Res. Code Ann. § 36.002(1)**

182. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

183. Defendants knowingly made, or caused to be made, and continue to make or cause to be made, to an officer or employee of the State of Texas, a false statement and/or misrepresentation of a material fact that permitted Defendants to receive an unauthorized benefit and/or payment under the Medicaid program and/or receive a benefit/and or payment greater than the benefit or payment that was authorized by the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

184. As a direct and proximate result of the above conduct by Defendants, the State of Texas unwittingly made full payments and has suffered damages and therefore is entitled to

recovery as provided by the Texas Medicaid Fraud Prevention Act in an amount to be determined at trial, plus a civil penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

**COUNT V**

**Violation of Tex. Hum. Res. Code Ann. § 36.002(2)**

185. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

186. Defendants, through their own acts or through the acts of their agents, knowingly made, used, or caused to be made or used, and continue to make, use, or cause to be made or used, a false record or statement to get false or fraudulent claims paid or approved by the Government in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

187. Defendants' materially false records or false statements are set forth above and include, but are not limited to, false electronic claims submitted to the government health programs, false certifications of the truthfulness and accuracy of claims submitted, and the provision of drugs and therapies to beneficiaries that were not medically necessary in order to get false or fraudulent Medicare and Medicaid claims paid or approved by the United States.

188. As a direct and proximate result of the above conduct by Defendants, the State of Texas unwittingly made full payments and has suffered damages and therefore is entitled to recovery as provided by the Texas Medicaid Fraud Prevention Act in an amount to be determined at trial, plus a civil penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

**COUNT VI**

**Violation of Tex. Hum. Res. Code Ann. § 36.002(7)(B)**

189. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

190. Defendants knowingly made or caused, and continue to make or cause, a claim under the Medicaid program for a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(B).

191. Defendants' claims for inappropriate services and products are set forth above and include, but are not limited to, claims for Rituximab, intravenous immune globulin, and testosterone administered to Medicaid beneficiaries far in excess of generally recognized standards.

192. As a direct and proximate result of the above conduct by Defendants, the State of Texas unwittingly made full payments and has suffered damages and therefore is entitled to recovery as provided by the Texas Medicaid Fraud Prevention Act in an amount to be determined at trial, plus a civil penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

**COUNT VII**

**Violation of Tex. Hum. Res. Code Ann. § 36.002(12)**

193. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

194. Defendants knowingly made, used, or caused, and continue to make, use, or

cause, false records or statements material to their obligation to pay or transmit money or property to this state under the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(12).

195. Defendants knowingly concealed, improperly avoided, or decreased, and continue to conceal, improperly avoid, or decrease, their obligation to pay or transmit money or property to the State of Texas under the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(12).

196. As a direct and proximate result of the above conduct by Defendants, the State of Texas unwittingly made full payments and has suffered damages and therefore is entitled to recovery as provided by the Texas Medicaid Fraud Prevention Act in an amount to be determined at trial, plus a civil penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

### **COUNT VIII**

#### **Violation of Tex. Hum. Res. Code Ann. § 36.002(13)**

197. Relator alleges and incorporates all paragraphs of this Amended Complaint set forth above as if fully set forth herein.

198. Defendants knowingly engaged in conduct that constitutes a violation under Section 32.039(b), in violation of Tex. Hum. Res. Code Ann. § 36.002(13). Tex. Hum. Res. Code Ann. § 32.039(b)(1) (prohibiting one from presenting, or causing to be presented, to the State of Texas a claim that contains a statement or representation the person knows or should know to be false).

199. As stated above, Defendants knowingly made, or caused to be made, and continue to make or cause to be made, to an officer or employee of the State of Texas, a false

statement and/or misrepresentation of a material fact that permitted Defendants to receive an unauthorized benefit and/or payment under the Medicaid program and/or receive a benefit/and or payment greater than the benefit or payment that was authorized by the Medicaid program.

200. As a direct and proximate result of the above conduct by Defendants, the State of Texas unwittingly made full payments and has suffered damages and therefore is entitled to recovery as provided by the Texas Medicaid Fraud Prevention Act in an amount to be determined at trial, plus a civil penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted.

### **PRAYER FOR RELIEF**

WHEREFORE, Relator respectfully requests that this Court enter judgment against Defendant as follows:

- (a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged in this Complaint, as the Civil False Claims Act, 31 U.S.C. §3729 *et seq.* provides;
- (b) That civil penalties of \$5,500 to \$11,000 be imposed for each and every false claim that the Defendants caused to be presented to the United States;
- (c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses that Relator necessarily incurred in bringing this case;
- (d) That the State of Texas be awarded damages in an amount to be determined at trial, plus a civil money penalty in the amount of \$5,000 to \$15,000 for each of the false claims submitted;

- (e) That civil penalties in an amount to be determined at trial be imposed on Defendant parent corporations for failing to return overpayments received for Defendant Costa's fraudulent and medically unnecessary services
- (f) That this Court award such other and further relief as it deems proper.

September 21, 2018

Respectfully submitted,

/s/ Charles S. Siegel

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/s/ David L. Haron

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ATTORNEYS FOR RELATOR

**CERTIFICATE OF SERVICE**

The undersigned counsel hereby certifies that a true and correct copy of the foregoing document, and all related attachments, was served via electronically through the CM-ECF (Electronic Case Filing) system to all counsel of record and to those registered to receive a Notice of Electronic Filing for this case on this the 21st day of September, 2018.

/s/ Charles S. Siegel